Standard Operating Procedure –

Conduct of a Clinical Research Study under the caBIG™ Program

This cover sheet controls the layout and components of the entire document.

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Note: This document will be issued for training on the Issue Date. The document will become available for use to trained personnel on the Effective Date. Before using this document, make sure it is the latest revision. Access the caBIG™ website to verify the current revision.

Revision History

Revision	Date	Author	Change Reference	Reason for Change
1.0	09/19/2005	SOP Working Group	N/A	Initial release.
2.0	10/30/2006	BP SIG/SOP WG	All pages	Annual update.

1. Purpose

This Standard Operating Procedure (SOP) describes the process for providing a consistent approach for conducting a clinical research study under the caBIG™ Program.

2. Scope

This SOP applies to the conduct of all clinical trial research studies covered under the caBIG™ program and sponsored by the National Cancer Institute (NCI).

3. Requirements

3.1 The clinical research study has been set-up according to the applicable SOPs.

3.2 The set-up of the study in the clinical data management application has been approved by the clinical study team and has been activated for production data collection.

4. References/Regulations/Guidelines

Section	SOP Number	Title
4.1	N/A	CDISC Glossary
4.2	AD-004	SOP for Information Security Compliance
4.3	AD-005	SOP for Protecting Patient Privacy
4.4	CR-007	SOP for Reconciliation of Serious Adverse Events
4.5	CR-003	Develop and Manage CRFs
4.6	CR-006	Coding of Clinical Research Data
4.7	CR-008	Study Close SOP
4.8	CR-009	Clinical Data Management Plan Guideline

5. Roles & Responsibilities

Role	Responsibility
Study Coordinator/Clinical Data Manager	• Maintain and update the study plan for managing clinical data collected in accordance with protocol specifications and/or requirements.

Role	Responsibility
	• Receive data and log receipt of CRFs in a timely and appropriate manner. • Transfer or hand-over received CRFs to the relevant entry personnel for processing. • Perform overall discrepancy resolution and data validation checks in line according to agreed timelines. • Resolve all coding issues prior to locking the database. • Reconcile the SAE data with adverse event data collected in the clinical study in line with the SOP on SAE Reconciliation. • Create, submit and manage queries to investigator or clinicians monitoring the clinical research trial. • Manage data updates and/or query closure(s) responses from the investigator or monitoring personnel. • Manage the timely loading of electronic data from external sources (e.g., patient positions, site and investigator information from C3PR; laboratory data; or, other electronically submitted data for the conduct of the clinical trial). • Manage clinical study conduct activities through data freeze and lock activities. • Manage the export of extract data views or datasets to clinical trials personnel (e.g., statistician for analysis; PI or clinical monitoring personnel for data review; QC for audit activities, etc.). • Ensure coding of data are consistent with the coding guidelines as detailed in the plan for the specific study. • Log all coding discrepancies or non-matches. • Take action on coding discrepancies with the Drug Safety Office in a timely and consistent manner for resolution. • Manage timelines for issue resolution and communicate coding review completion to clinical data manager.
Data Entry Personnel	• Input CRF response data received in line with this SOP. • Manage the timelines for completion of the data entry activities to meet study milestones. • Flag or indicate any outstanding data entry issues or items for review and resolution by data management or clinical monitoring personnel. • Update data, when applicable, and when access is appropriately assigned.
Principal Investigator	• Review data queries to respond to concerns or questions from clinical data management. • Resolve queries by appropriate means (e.g., data correction; no additional information; data recorded is correct). • Contact the clinical data manager if additional clarification is required. • Resolve with Clinical Data Manager any clarification issues.
Drug Safety Officer	• Provide input required during coding review in a timely and

Role	Responsibility
	adequate manner and according to request submitted. • Provide all drug safety input required for resolution of coding review issues. • Assist in reconciling the adverse events captured in the Safety Database with the adverse events captured in the clinical data database - in line with SOP on SAE Reconciliation. • Assure drug safety requirements are met according to protocol requirements and regulations, prior to unblinding.
Local QA Personnel	• Assure all data are entered and cleaned in line with the GCP guidelines. • Audit data to verify all quality standards are met during performance of the process. • Suggest necessary corrections and assure changes are implemented, making the rationale behind changes clear and fully understood. • Provide detailed advice / guidance on any data quality matters. • Assure that error levels meet the predetermined acceptable levels as defined in the study plan. • Indicate areas of further quality improvement, document recommendations and provide input on issues to the clinical research team members.
Study Statistician	• Assure that there is sufficiently clean data on subjects to run analysis programs. • Work with clinical data manager to update study plan if the statistical analysis plan changes and if those changes reflect collection request for data or new CDEs.
Programmer	• Review and test analysis programs for functionality, utilizing identified test data and assure that the testing process is closely monitored throughout. • Resolve any analysis program malfunctions to ensure optimal program performance. • Modify analysis programs in line with input from Statistician and following the relevant specifications.
Applications Support	• Provide the QA team with appropriate rights to the database to perform its QA activities in an uninterrupted and consistent way. • Remove all access rights from the relevant personnel once the data is frozen or locked or personnel leave the team. • Communicate completion of removal of rights to target audience.
Application's Standards Librarian	• Update the application's standards library with any new reusable programs created during Study Conduct activities.

6. Attachments

This SOP will be used in conjunction with the following attachments. These attachments must be used by all research sites conducting clinical trials under the caBIG™ Program and can be customized by individual research sites to accommodate format and content in accordance with local guidelines and/or requirements.

Title	Description
1) Procedure Description for Study Conduct	This document provides instructions for conducting studies in a clinical data management application under the caBIG™ Program. It provides step-by-step guidance to ensure that all studies are conducted in a consistent manner.
2) Process Flow for Study Conduct	This document identifies the workflow activities, by role, for the steps identified in the Procedure for Study Conduct.